

We Claim:

1. A method for determining a prognosis of disease free or overall survival in a patient suffering from cancer, said method comprising:

5 (a) determining a BAG gene expression level in a cancerous tissue sample or body fluid from said patient; and

(b) classifying said patient as belonging to either a first or second group of patients, wherein said first group of patients having high levels of expression of the BAG gene is classified as having a different likelihood of suffering tumor recurrence or spread than said second group of patients having low levels of expression of the BAG gene.

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2. The method of claim 1, wherein said first group of patients having high levels of expression of the BAG gene are classified as having a decreased risk of tumor recurrence or spread compared to said second group of patients having low levels of expression of the BAG gene.

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3. The method of claim 1, wherein said first group of patients having high levels of expression of the BAG gene are classified as having an increased risk of tumor recurrence or spread compared to said second group of patients having low levels of expression of the BAG gene.

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4. The method of claim 1, wherein said second group of patients having low levels of expression of the BAG gene are classified as having a decreased risk of tumor recurrence or spread compared to said first group

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of patients having high levels of expression of the BAG gene.

5 5. The method of claim 1, wherein said second group of patients having low levels of expression of the BAG gene are classified as having an increased risk of tumor recurrence or spread compared to said first group of patients having high levels of expression of the BAG gene.

10 6. The method of claim 1, wherein said expression level of the BAG gene is determined by measuring the amount of the BAG mRNA transcript or BAG protein.

15 7. The method of claim 6, wherein said measuring the amount of BAG protein is with an agent that binds BAG protein.

8. The method of claim 7, wherein said agent is an antibody specific for the BAG protein.

9. The method of claim 7, wherein said BAG protein is BAG-1.

20 10. The method of claim 7, wherein said BAG protein is BAG-1N.

25 11. The method of claim 6, wherein said expression level of the BAG gene is determined by measuring the amount of BAG protein product using an immunoassay.

12. The method of claim 11, wherein said immunoassay is an immuno-polymerase chain reaction (immuno-PCR) assay.

Sub D3
13. The method of claim 1, wherein said level of expression of the BAG gene is determined prior to lymph node involvement of said cancer.

14. The method of claim 1, wherein said level of expression of the BAG gene is determined after lymph node involvement of said cancer.

10 15. The method of claim 1, wherein said level of expression of the BAG gene is determined during Stage I or Stage II of said cancer.

Sub A1
16. A method for prognosis of disease-free or overall survival of an individual having a cancer tumor, comprising determining the level of BAG expression in a sample of said tumor or a body fluid, wherein a high level of expression correlates positively with disease-free or overall survival.

17. The method of claim 16, wherein said cancer is breast cancer.

Sub D5
Sub A2
18. The method of claim 16, wherein said level of BAG expression is determined by measuring the level of mRNA which encode said BAG protein.

Sub D5
19. The method of claim 16, wherein said level of BAG expression is determined by measuring BAG protein levels.

20. The method of claim 16, wherein said level of BAG expression is determined by measuring the level of BAG protein that is detectable in samples selected from the group consisting of breast tumor tissue, blood, serum, and plasma.

21. The method of claim 16, further comprising determining if said level of BAG expression represents an overproduction that is above a reference level of BAG expression.

22. The method of claim 21, wherein said reference level of BAG expression is determined by a histogram analysis.

23. The method of claim 21, wherein said reference level of BAG expression is determined relative to a level of BAG expression produced by *in vitro* cultured cells which produce BAG.

24. The method of claim 21, wherein said reference level of BAG expression is determined relative to a level of BAG expression in non-cancerous cells.

25. A method for predicting the risk of tumor recurrence or spread in an individual having a cancer tumor, comprising determining whether BAG protein is produced in a sample of said tumor or body fluid from said individual, such a production correlating negatively with a likelihood of tumor recurrence or spread.

26. The method of claim 25, further comprising:

5 (a) determining an overproduction level for BAG protein, said level being in excess of a minimum amount statistically determined to be indicative of decreased likelihood of tumor recurrence or spread;

(b) determining the level of BAG expression in said tumor sample; and

10 (c) predicting said risk of tumor recurrence or spread wherein an overproduction level of BAG protein in the tumor sample is negatively associated with the likelihood of tumor recurrence or spread.

15 27. A method for screening a cancer patient to determine the risk of tumor metastasis, said method comprising:

20 (a) determining the level of amplification or expression of the BAG gene in a cancerous tissue sample or a body fluid sample from said patient; and

25 (b) classifying a patient having high levels of amplification or expression of the BAG gene, relative to a reference level, as being less likely to suffer tumor metastasis or having an increased chance of survival.

28. The method of claim 27, wherein said cancer is breast cancer.

29. The method of claim 27, wherein BAG amplification is measured with a probe specific for the BAG gene.

Sub D6
5 30. The method of claim 27, wherein gene expression is determined by measuring the amount of BAG mRNA transcription.

31. The method of claim 27, wherein gene expression is determined by measuring the amount of BAG protein.

10 32. The method of claim 31, wherein the amount of BAG protein is measured using an immunoassay.

33. The method of claim 32, wherein said immunoassay is an immuno-polymerase chain reaction assay.

34. A method for determining the proper course
15 of treatment for a patient suffering from cancer, said method comprising:

(a) determining the level of BAG gene expression in a cancerous tissue sample or body fluid from said patient;

Sub A5
20 (b) identifying a first group of patients having low levels of BAG gene expression, which first group of patients may require treatment proper for patients having a lesser chance of survival or decreased time to tumor recurrence
25 or spread; and

(c) identifying a second group of patients having high levels of BAG gene expression, which second group of patients may require treatment proper for patients having a greater chance of survival and being less likely to suffer tumor recurrence or spread.

35. The method of claim 34, wherein said level of BAG gene expression is determined by measuring the amount of BAG mRNA transcript or BAG protein.

10 36. The method of claim 34, wherein said level of BAG gene expression is determined prior to lymph node involvement.

15 37. The method of claim 34, wherein said level of expression of the BAG gene is determined after lymph node involvement of said cancer.

38. A kit for use in the method of claim 1, which includes one or more agents, each of which specifically bind to BAG protein, or fragments thereof.

20 39. The kit of claim 38, wherein said one or more agents comprise one or more antibodies.

40. A kit for use in the method of claim 1, which includes one or more nucleic acids, each of which specifically bind to BAG mRNA.

41. A reagent for use in the method of claim 1, comprising an antibody which specifically binds to the BAG protein, or fragments thereof.

42. The method of claim 1, wherein said cancer
5 is breast cancer.

43. A method for determining a prognosis in a patient suffering from cancer, said method comprising:

(a) determining the level of expression of BAG in cancerous tissues of a patient; and

10 (b) classifying said patient as belonging either to a first group of patients having high levels of expression of BAG, or a second group of patients having low levels of expression of BAG;

15 wherein said first group and said second group have differing prognoses for tumor recurrence or spread.

20 44. The method of claim 43, wherein said first group has a lower likelihood of tumor recurrence or spread than said second group.

25 45. The method of claim 43, wherein said cancer is breast cancer.

46. A method for determining a prognosis in patients suffering from cancer, said method comprising classifying a first group of cancer patients having high
25 levels of amplification or expression of BAG as having a

different likelihood of tumor recurrence or spread than a second group of patients having low levels of amplification or expression of BAG.

47. A method for monitoring the effectiveness of a course of treatment for a patient suffering from cancer, said method comprising:

(a) determining a first BAG gene expression level in a cancerous tissue sample or a body fluid sample from said patient prior to said treatment; and

(b) subsequently determining a second BAG gene expression level in a cancerous tissue sample or a body fluid sample from said patient during said treatment; and

whereby comparison of said first BAG expression level with said second BAG expression level indicates the effectiveness of said treatment.

48. A method for determining a prognosis of disease free or overall survival in a patient suffering from cancer, said method comprising:

(a) determining a BAG activity level in a cancerous tissue sample or body fluid sample from said patient; and

(b) classifying said patient as belonging to either a first or second group of patients, wherein said first group of patients having high levels of BAG activity is classified as having a different likelihood of suffering tumor recurrence or spread than said second

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